

REMARKS

The Office Action mailed on December 6, 2007 has been reviewed, along with the art cited. Claims 1-23 and 90 are pending in this application.

Rejections Under 35 U.S.C. § 112

Claims 1-23 and 90 were rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated “the limitation ‘not synchronized with the patient’s gait’ is unclear.” Office Action pg. 3 ¶ 4. Applicant respectfully traverses this assertion.

The present application states, with regards to one embodiment of a method of improving gait, that “The contraction of the muscle is not coincident with the prompt as would be the case with functional electrical stimulation. The cues are of insufficient amplitude to meet motor thresholds to induce contractions and are of inadequate duration to facilitate fused contractions. Unlike with functional electrical stimulation patients perform better when they do not attempt to synchronize with the cues.” ¶ 71. Applicant asserts that, based at least on the statement above, one of ordinary skill in the art would understand the meaning of “not synchronized with the patient’s gait.” Therefore, the limitation is clear and apprises one of ordinary skill in the art as to the scope of the claims. Applicant, therefore, requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1, 3, 9-13, 16, 18-21, and 23 were rejected under 35 USC § 102(a) as being anticipated by Larson et al, (U.S. Patent No. 4,697,808). Applicant respectfully traverses these rejections.

Claim 1 reads:

A method of improving a patient’s gait, the method comprising:
producing a plurality of stimulation prompts at a plurality of stimulation points using multiple stimulation channels;

wherein the plurality of stimulation points are located symmetrically on each leg;
applying the plurality of stimulation prompts in a timed periodic fashion across
the plurality of stimulation points;

wherein the plurality of stimulation prompts are not synchronized with the
patient's gait;

wherein each of the multiple stimulation channels is associated with a stimulation
electrode at one of the plurality of stimulation points; and

activating a return electrode whenever one of the multiple stimulation channels on
an associated leg is active.

Applicant asserts that Larson does not teach or suggest all the claimed limitations of claim 1. In particular, Larson does not teach or suggest "wherein the plurality of stimulation prompts are not synchronized with the patient's gait." In rejecting claim 1, the Examiner asserted that Larson teaches "wherein the prompts are not synchronized with the patient's gait (i.e. for standing; col. 5, line 44)." OA pg. 4 ¶ 7. Also, the Examiner "is interpreting the 'standing' as being 'not synchronized with the patient's gait.'" *Id.* Furthermore, the Examiner asserted that "Larson discloses that 'the body has an inherent time lag of about 100 milliseconds in responding to stimulation', which means that the gait response is not synchronous with stimulation." OA pg. 5 ¶ 7. Applicant respectfully traverses these assertions.

According to the Examiner's stated interpretation, "standing" is separate from the "patient's gait." Therefore, stimulation provided for "standing" is not stimulation for a "patient's gait." However, claim 1 is directed to "a method of improving a patient's gait." Hence, using the Examiner's interpretation, the patient's gait should be compared to stimulation for the patient's gait, not to stimulation for patient standing, in order to determine if the stimulation is synchronized with the patient's gait.

With regards to the inherent time lag, Larson states "For any large change in stimulation voltage, proportional software time lags are introduced. ***This allows for time lags in physiological response to stimulation.*** It has been found that the body has an

inherent time lag of about 100 milliseconds in responding to stimulation, and software time lags are necessary in order to avoid unstable oscillation.” Col. 6, lines 4-21. Hence, contrary to the Examiner’s assertion, the body’s inherent time lag does not mean that the “the gait response is not synchronous with stimulation.” Rather, Larson discusses compensating for the body’s inherent time lag with software time lags “in order to avoid unstable oscillation.”

Furthermore, with regards to standing, Larson states:

After the handicapped person has activated standing control button 111, the computer causes application of ramped control signals to electrodes positioned for stimulation of both the left and right quadriceps muscles. ***During this ramping action***, the computer monitors the flexion angles for both knees . . . ***Stimulated extension of both knees proceeds*** under full closed loop control ***until*** the feedback sensors indicate that the knees are near a locked position. . . After knee-lock has been achieved, the computer applies a ramp signal to the left and right gluteus maximus muscle groups and also to the left and right hamstring muscle groups. ***This causes simultaneous extension*** of both hips, so that the handicapped person assumes the posture illustrated in FIG. 3D. Ramping of the hip extension muscles proceeds on an open loop basis until micro-switches 119 and 121 at the left and right hips respectively indicate that an erect posture has been achieved. The computer then ***maintains stimulation*** at a constant level ***while*** the handicapped person manually engages locking levers 185 in both of hip joints 34, 36, at which time cable assemblies 44, 46 maintain an erect body posture without computer stimulation. Col. 5, line 44 – Col. 6, line 10.

Similarly, with regards to walking, Larson states “The stimulation wave form utilized for walking . . . consists of a slow ramp up, a plateau and a slow ramp down . . . The amplitude of the wave ***controls*** the strength of the muscle contractions and ***the speed of leg movement*** while the period of the wave ***controls the duration of the muscle contractions and the duration of the steps***.” Col. 6, line 66 – col. 7, line 9. However, with regards to one embodiment of a method of improving gait, the present application states that “***The contraction of the muscle is not coincident with the prompt*** as would be the case with functional electrical stimulation. The cues are of insufficient amplitude to meet motor thresholds to induce contractions and are of inadequate duration to facilitate

fused contractions. Unlike with functional electrical stimulation patients perform better *when they do not attempt to synchronize with the cues.*” ¶ 71.

Since stimulation waves in Larson control “the duration of the muscle contractions,” the stimulation waves are synchronized with the muscle contraction even without compensation for the body’s inherent time lag. In particular, stimulation provided for standing is synchronized with the patient’s standing motion and stimulation provided for walking is synchronized with the patient’s walking motion. Therefore, for the reasons stated above, Larson does not teach or suggest “wherein the plurality of stimulation prompts are not synchronized with the patient’s gait” as claimed in claim 1. Claim 1, therefore, is not anticipated by Larson and Applicant requests that the rejection be withdrawn.

Claims 3, 9-13, 16, 18-21, and 23 depend from claim 1 and, thus, are allowable for at least the reasons stated above with regards to claim 1. Applicant, therefore, requests that the rejections be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 2, 7, 8, 14, 15, 17, 22, and 90 were rejected under 35 USC § 103(a) as being unpatentable over Larson et al, (U.S. Patent No. 4,697,808). Applicant respectfully traverses these rejections.

Claim 90 reads:

A method of reducing habituation in improving a patient’s gait, the method comprising:

producing a plurality of stimulation prompts at a plurality of stimulation points using multiple stimulation channels;

wherein the plurality of stimulation points are located symmetrically on each leg;

applying the plurality of stimulation prompts in a timed periodic fashion across the plurality of stimulation points;

wherein the plurality of stimulation prompts are not synchronized with the patient’s gait;

wherein each of the multiple stimulation channels is associated with a stimulation electrode at one of the plurality of stimulation points; and

activating a return electrode whenever one of the multiple stimulation channels on an associated leg is active;

linearly changing a pulse period for the plurality of stimulation prompts.

Applicant asserts that Larson does not teach or suggest all the claimed limitations of claim 90. In particular, Larson does not teach or suggest “wherein the plurality of stimulation prompts are not synchronized with the patient’s gait.” In rejecting claim 90, the Examiner asserted that “Larson discloses the essential features of the claimed invention.” OA pg. 5 ¶ 11. With reference to the Examiner’s arguments related to claim 1, the Examiner asserted that Larson teaches “wherein the prompts are not synchronized with the patient’s gait (i.e. for standing; col. 5, line 44).” OA pg. 4 ¶ 7. Also, the Examiner “is interpreting the ‘standing’ as being ‘not synchronized with the patient’s gait.’” *Id.* Furthermore, the Examiner asserted that “Larson discloses that ‘the body has an inherent time lag of about 100 milliseconds in responding to stimulation’, which means that the gait response is not synchronous with stimulation.” OA pg. 5 ¶ 7. Applicant respectfully traverses these assertions.

According to the Examiner’s stated interpretation, “standing” is separate from the “patient’s gait.” Therefore, stimulation provided for “standing” is not stimulation for a “patient’s gait.” However, claim 1 is directed to “a method of improving a patient’s gait.” Hence, using the Examiner’s interpretation, the patient’s gait should be compared to stimulation for the patient’s gait, not to stimulation for patient standing, in order to determine if the stimulation is synchronized with the patient’s gait.

With regards to the inherent time lag, Larson states “For any large change in stimulation voltage, proportional software time lags are introduced. ***This allows for time lags in physiological response to stimulation.*** It has been found that the body has an inherent time lag of about 100 milliseconds in responding to stimulation, and software time lags are necessary in order to avoid unstable oscillation.” Col. 6, lines 4-21. Hence,

contrary to the Examiner's assertion, the body's inherent time lag does not mean that the "the gait response is not synchronous with stimulation." Rather, Larson discusses compensating for the body's inherent time lag with software time lags "in order to avoid unstable oscillation."

Furthermore, with regards to standing, Larson states:

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Since stimulation waves in Larson control “the duration of the muscle contractions,” the stimulation waves are synchronized with the muscle contraction even without compensation for the body’s inherent time lag. In particular, stimulation provided for standing is synchronized with the patient’s standing motion and stimulation provided for walking is synchronized with the patient’s walking motion. Therefore, for the reasons stated above, Larson does not teach or suggest “wherein the plurality of stimulation prompts are not synchronized with the patient’s gait” as claimed in claim 90. Claim 90, therefore, is not anticipated by Larson and Applicant requests that the rejection be withdrawn.

Claims 2, 7, 8, 14, 15, 17, and 22 depend from claim 1 and, thus, inherit the limitations of claim 1 discussed above. As stated above with regards to claim 1, nothing in Larson teaches or suggests “wherein the plurality of stimulation prompts are not synchronized with the patient’s gait.” Therefore, for at least the reasons stated above with regards to claim 1, claims 2, 7, 8, 14, 15, 17, and 22 are not obvious over Larson. Applicant, therefore, requests that the rejections be withdrawn.

Allowable Subject Matter

Claims 4-6 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, in light of the arguments made above, claims 4-6 have not been amended.

Serial No.: 10/693,792

Filing Date: 10/24/2003

Attorney Docket No. 105.007US01

Title: SYSTEMS AND METHODS FOR TREATING MOVEMENT DISORDERS

CONCLUSION

Applicant respectfully submits that claims **1-23 and 90** are in condition for allowance and notification to that effect is earnestly requested. If necessary, please charge any additional fees or credit overpayments to Deposit Account No. 502432.

If the Examiner has any questions or concerns regarding this application, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

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